IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	)	
Plaintiffs,	)	
	)	C.A. No. 06-286 (GMS)
v.	)	
BARR LABORATORIES, INC.	)	
Defendant.	)	

DEFENDANT BARR LABORATORIES, INC.'S
OPENING CLAIM CONSTRUCTION BRIEF

Dated: September 10, 2007

Josy W. Ingersoll (I.D. #1088)
Karen L. Pascale (I.D. #2903)
Karen E. Keller (I.D. #4489)
YOUNG CONAWAY STARGATT & TAYLOR, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801
Tel: (302) 571-6672
Fax: (302) 571-1253

George C. Lombardi
Maureen L. Rurka
Julia M. Mano
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601

Robert C. Millonig
Eldora L. Ellison
Laura A. Vogel
STERNE KESSLER GOLDSTEIN & FOX PLLC
1100 New York Avenue, N.W.
Washington, D.C. 20005

Attorneys for Defendant Barr Laboratories, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

SUMMARY OF THE ARGUMENT

1. The crux of the *Markman* dispute here centers on the parties' opposing interpretations of the claimed "thixotropic" nature of the invention allegedly disclosed in the patents-in-suit, U.S. Patent Nos. 5,976,573 (the "'573 patent") and 6,143,329 (the "'329 patent"). Barr's approach – to interpret the term "thixotropic" in accordance with the patent claims, specification and prosecution history – is manifestly the proper one. While Barr seeks to hold Plaintiffs to the representations made in the specification and prosecution history, Plaintiffs seek to erase those representations as if they never occurred. Indeed, Plaintiffs ignore the claims, specification and prosecution history, instead relying on a general definition of "thixotropic" from an extrinsic textbook. Plaintiffs' proposed constructions are divorced from the disclosures in the specification and contradicted by the statements made to the United States Patent and Trademark Office during the course of patent prosecution. As such, they are incorrect.

2. The Federal Circuit has made it clear that the patent's specification drives the claim construction analysis because the "claims are directed to the invention that is described in the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*) (quotation omitted). The claims "do not have meaning removed from the context" of the specification and prosecution history and the "patent system is based on the proposition that claims cover only the invented subject matter." *Id.* at 1316, 1321. Accordingly, the proper focus in claim construction, reflected in Barr's construction, is on the intrinsic record – the claim language, the specification and the prosecution history. Proper claim construction does not entail bypassing the intrinsic record in favor of a general definition from an extrinsic source at odds with the intrinsic record, as Plaintiffs urge. *Id.* at 1319.

3. The parties also dispute the meaning of the claim terms "aqueous pharmaceutical composition" and "pharmaceutically effective amount." Barr's proposed constructions comport

with the ordinary meaning of these terms. Plaintiffs' constructions do not, again contrary to controlling Federal Circuit precedent on claim construction.

4. For these reasons, as detailed more fully below, the Court should adopt Barr's proposed constructions, which are the only ones that are consistent with the claim language, written description, prosecution history, and purpose of the invention.

STATEMENT OF FACTS

The patents spring from the premise that, to maximize effectiveness, a drug for topical treatment of nasal allergies should deposit on all target tissues of the nasal cavity and should remain in contact with those target tissues for an extended period of time. (A4 at col. 1:5-10.)[1] In an attempt to achieve this goal when formulating its brand product, Nasacort® AQ, Plaintiffs employed a commercially-available suspending agent, Avicel® CL-611, that causes the formulation to be a viscous gel when standing, to reduce viscosity and become liquid when shaken for spraying into the nasal cavity, and then ostensibly to return to a viscous gel when sprayed into the nasal cavity. (A5 at col. 4:28-62; A8 at col. 9:14-15.) The theory is: when the formulation becomes liquid after shaking, it will form a sprayed mist that will spread out and deposit on all of the target tissues in the nasal cavity. When the formulation is deposited on those target tissues, it will be a thick gel that will resist being cleared from the cilia that normally function to clear the nasal cavity. (A5 at col. 4:28-62.) Much of the specification is dedicated to describing these characteristics of the formulation in greater detail.

More specifically, the patents are directed to an aqueous pharmaceutical composition containing triamcinolone acetonide, or "TAA," as the active ingredient. (A4 at cols. 1:31-32,

[1] The '329 patent is a continuation of the application from which the '573 patent issued. The two patents share a common specification. Accordingly, unless otherwise indicated, this brief will cite to the '573 patent specification.

2:40-42.) The composition can be sprayed into the nasal cavity of a human being where the TAA is effective in treating an abnormal bodily condition topically – that is, by its presence on the mucosal surfaces that line the nasal cavity. (A4 at col. 1:5-10.) The only abnormal bodily condition specifically identified is nasal allergies, or "allergic rhinitis." (A4 at col. 1:11-13, 1:17-28.) The relevant patent claims further claim (1) an article of manufacture with a spray pump and a vessel that contains the composition and (2) a method of using the composition.[2] (A10-A11 at cols. 14:45-16:25; A21-A22 at cols. 13:36-16:24.)

According to the patents, the claimed invention "affords numerous and important advantages in the treatment of a condition that involves application of a medicament to the surface of the mucosa which line the nasal cavities." (A5 at col. 3:15-18.) The patents explain that TAA is a steroidal anti-inflammatory agent used to treat allergic rhinitis generally "by spraying it into the nasal passages of the human patient where it deposits on surfaces of the mucosa which line the nasal cavities." (A4 at col. 1:32-35.) A TAA-containing nasal spray needs a "combination of desired properties" in order to have maximum effectiveness. (A4 at col. 1:39-41.) The composition should be "such that the [TAA] is delivered readily to all portions of the nasal cavities (the target tissues) where it performs its pharmacological function." (A4 at col. 1:41-45.) Moreover, the TAA "should remain in contact with the target tissues for relatively long periods of time." (A4 at col. 1:45-47.) The patents explain:

> The longer the medicament remains in contact with the target tissues, the greater the opportunity for the medicament to perform its function. In order to remain in contact with the target tissues, the medicament must be capable of resisting those forces in the nasal passages that function to remove particles from the nose. Such forces, referred to as 'mucocillary clearance,' are recognized as being extremely effective in removing particles from the nose in a rapid manner, for example, within 10-30 minutes from the time the particles enter the nose.

[2] Plaintiffs have asserted claims 1-10, 21-24, 26-30 and 34-35 of the '573 patent and claims 1, 3-17, and 22-26 of the '329 patent.

(A4 at col. 1:47-57.)

The patents disclose a composition that they say will deliver the TAA "readily to the many portions of the nasal cavity where it can perform its pharmacological function." (A5 at col. 3:21-22.) And, furthermore, the TAA "remains in contact with the target tissues for relatively long periods of time, for example, at least about an hour and for even two or more hours." (A5 at col. 3:22-25.) The patented composition achieves these goals by employing a suspending agent "which maintains the particles of medicament suspended in the composition during non-use and during spray of the composition into the nasal cavity, and also when the composition is deposited on the mucosal surfaces of the nasal cavity." (A5 at col. 4:31-36.)

The suspending agent gives the composition "thixotropic" properties, described thusly:

- **During non-use:** "The thixotropic nature of the composition at rest (not subject to shear) can be described as a gel in which the particles of medicament are dispersed and suspended substantially uniformly. The viscosity of the composition at rest is relatively high, for example, about 400 to about 1000 cp." (A5 at col. 4:36-41.)

- **During spray of the composition into the nasal cavity:** "As the composition is subjected to shear forces, for example, upon being subjected to forces involved in its being agitated before spraying, the viscosity of the composition decreases (for example, to about 50 to about 200 cp) and it flows readily through the spray device and exits therefrom in the form of a fine plume which infiltrates and deposits on the mucosal surfaces of at least the following parts of the nose: the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses; and the turbinates which overlie the conchas of the nasal cavities. Thus, the thixotropic composition is such that it comprises a freely flowable liquid, and in sprayed form, a fine mist that finds its way to and deposits on the desired mucosa." (A5 at col. 4:41-53.)

- **When deposited on the mucosal surfaces of the nasal cavity:** "In deposited and relatively unstressed form, the composition increases in viscosity and assumes its gel-like form which includes particles of the medicament suspended therein and which resists being cleared from the nasal passages by the inherent mucocillary forces that are present in the nasal cavities." (A5 at col. 4:54-60.)

The patent continues by further defining the viscosities displayed by the composition:

> For convenience, the viscosity of the composition at rest is referred to as the "setting viscosity" and the viscosity of the composition which is shaken is referred to as the "shear viscosity." As mentioned above the setting viscosity of the composition should be sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition and to retain for an extended period of time the composition on the mucosal surfaces on which it is deposited in the nasal cavities, that is, the composition resists being swept away by the mucocillary forces which are present in the nasal cavities. The shear viscosity of the composition is sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist.

(A5-A6 at cols. 4:63-5:9.) Thus, the composition of the invention exhibits two viscosities: a "setting viscosity" at rest and in deposited form in the nasal cavities, and a "shear viscosity" when shaken in preparation for spraying.

ARGUMENT

I. Claim Construction Standard: Claims Must Be Construed In Accordance With The Specification And Prosecution History.

Claim construction is a pure question of law whereby the court determines the scope and meaning of the claim limitations. *Markman v. Westview Instruments Inc.*, 52 F.3d 967, 970-71, 978 (Fed. Cir. 1995) (en banc); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455-56 (Fed. Cir. 1998) (en banc). "It is a 'bedrock principle' of patent law that 'the *claims* of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)) (emphasis added).

The Federal Circuit recently clarified the principles by which district courts should approach claim construction analysis. *See Phillips*, 415 F.3d 1303. The starting place in claim construction is the language of the claims themselves. Claim terms are usually given "their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312-13. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of

the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313; *see also Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1302 (Fed. Cir. 2005).

Thus, the specification is critical to claim construction. *Phillips*, 415 F.3d at 1315. In fact, the specification is "the single best guide to the meaning of a disputed term." *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The "claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose." *Id.* at 1316 (quoting *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001)). Under *Phillips* and its progeny, the patentee "is not entitled to a claim construction divorced from the context of the written description and prosecution history." *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1144-45 (Fed. Cir. 2005). "[T]he scope and outer boundary of claims is set by the patentee's description of his invention," and "the claims cannot be of broader scope than the invention that is set forth in the specification." *On Demand Machine Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1337-38, 1340 (Fed. Cir. 2006). For these reasons, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Phillips*, 415 F.3d at 1317.

The presumption in favor of a claim term's ordinary meaning may be overcome, moreover, if "the patent expresses an intention to impart novel meaning to claim terms." *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302 (Fed. Cir. 2003). As the *Phillips* court recognized, "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess [and] . . . [i]n such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316.

In addition to consulting the specification, a district court should also consider the patent's prosecution history. *See Phillips*, 415 F.3d at 1317. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* The prosecution history is useful because it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

Moreover, the Federal Circuit has repeatedly stated that "[c]laims may not be construed one way in order to obtain their allowance and in a different way against accused infringers." *Southwall Techs, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995). In these situations, the court should not allow the patentee to game the system by construing claims one way during prosecution and another way in litigation; rather, the court should hold the patentee to its representations to the Patent Office. *See Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349-51 (Fed. Cir. 2004); *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) (patentee "must be held to the restrictive claim construction that was argued during prosecution").

Thus, when a patentee distinguishes the claimed invention over the prior art, "an applicant is indicating what the claims do not cover, he is by implication surrendering such protection." *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997); *see also Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998); *O.I. Corp. v. Tekmar Co., Inc.*, 115 F.3d 1576, 1581 (Fed. Cir. 1997) (limiting claim to non-smooth passage structures where the specification "expressly distinguishes over the prior art passages by stating that those passages are generally smooth-walled"); *Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d

1309, 1318 (Fed. Cir. 2006) (patentee is "not entitled to a claim construction divorced from the context of the written description and prosecution history").

In the hierarchy of interpretative sources, the final, and least reliable, category to which a court may turn is evidence extrinsic to the patent; that is, "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980; *Phillips,* 415 F.3d at 1318. Extrinsic evidence may be useful to explain the technological background of the patent or to explain how persons of ordinary skill in the art "might use" the claim terms, *Phillips,* 415 F.3d at 1318, but it should be disregarded where it is "clearly at odds with the claim construction mandated by the claims themselves . . . [and] the written record of the patent." *Id.* at 1318, 1320-24 (quotation omitted). Thus, although courts may resort to extrinsic evidence, such evidence cannot contradict or overcome the construction compelled by the intrinsic evidence. *Id.* at 1319.

II. The Patents Are Limited To The "Thixotropic" Properties Set Forth In The Claims And Specification.

The term "thixotropic" appears in every asserted claim of the patents. It is used in reference to the claimed composition in each of the three types of asserted claims – the composition claims themselves, the method of using the composition, and the article of manufacture containing the composition. The parties agree that the composition contains a suspending agent, which is the ingredient that "causes the composition to have thixotropic properties." (*See, e.g.*, D.I. 114, Joint Claim Chart, '573 patent at 2.) The parties disagree, however, on the meaning of the claim term "thixotropic" and the specific thixotropic properties the composition must exhibit. Barr's construction is properly grounded in the intrinsic record – the claims, the specification, and the prosecution history. Under Barr's construction, the term "thixotropic" is generally interpreted as described in the patent specification, with certain claims

containing additional terms that limit or describe the thixotropic properties that the composition must exhibit. Plaintiffs' construction, on the other hand, ignores the intrinsic record and relies on a definition from an extrinsic source.

A. The Claim Term "Thixotropic" Must Be Construed According To The Definition Set Forth In The Patents.

The parties construe the term "thixotropic" as follows:

Claim Term	Barr's Construction	Plaintiffs' Construction
thixotropic	At rest, the composition is a gel with a setting viscosity (or viscosity at rest) that is sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition. The composition has a shear viscosity (or viscosity when shaken) that becomes lower than the setting viscosity and sufficiently low to maintain the particles suspended in the composition and to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity, which is sufficiently high to maintain particles of medicament suspended therein and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity (including the anterior regions of the nose, frontal and maxillary sinuses and turbinates), i.e., the composition resists being swept away by the mucociliary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes.	"Thixotropic" refers to the characteristics of a composition which exhibits a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed.

Following the teachings in *Phillips*, Barr's construction of the term "thixotropic" comes directly from the patent specification and the applicant's representations to the Patent Office during patent prosecution concerning the scope of the claims. A review of the specification and

prosecution histories shows that the applicant set forth the specific thixotropic properties that the claimed composition must demonstrate. The applicant also told the Patent Office that the invention does not extend more broadly to any sort of general thixotropic behavior, as Plaintiffs now contend. Indeed, the specification here is conclusive as to the meaning of "thixotropic." *Phillips*, 415 F.3d at 1316 ("[The] claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose.") (quoting *Network*, 242 F.3d at 1352); *id.* at 1315 ("[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'") (*quoting Vitronics*, 90 F.3d at 1582).

1. The Specification Provides The Definition Of The Thixotropic Properties Of The Composition.

After discussing the water-based nature of the composition and the medicament, the specification's Detailed Description of the Invention proceeds in several paragraphs to detail the thixotropic properties of the composition. The specification begins this discussion of "the composition of the present invention" by noting the claimed suspending agent and its role in forming the thixotropic suspension:

> The composition of the present invention contains also a pharmaceutically acceptable excipient which is effective in forming a thixotropic suspension of the solid particles of medicament comprising the composition. The excipient is present in an amount which maintains the particles of medicament suspended in the composition during non-use and during spray of the composition in the nasal cavity, and also when the composition is deposited on the mucosal surfaces of the nasal cavities.

(A5 at col. 4:28-36.) The specification then proceeds to describe in greater detail "[t]he thixotropic nature of the composition":

> The thixotropic nature of the composition at rest (not subject to shear) can be described as a gel in which the particles of medicament are dispersed and suspended substantially uniformly. The viscosity of the composition at rest is relatively high, for example, about 400 to about 1000 cp. As the composition is

> subjected to shear forces . . . the viscosity of the composition decreases (for example, to about 50 to about 200 cp) and it flows readily through the spray device and exits therefrom in the form of a fine plume which infiltrates and deposits on the mucosal surfaces of at least the following parts of the nose: the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses; and the turbinates which overlie the conchas of the nasal cavities. Thus, the thixotropic composition is such that it comprises a freely flowable liquid, and in sprayed form, a fine mist that finds its way to and deposits on the desired mucosa. In deposited and relatively unstressed form, the composition increases in viscosity and assumes its gel-like form which includes particles of the medicament suspended in the composition and which resists being cleared from the nasal passages by the inherent mucocillary forces that are present in the nasal cavities. Tests have shown that amounts of the deposited composition remain on the mucosal surfaces for relatively long periods of time, for example, at least one hour and even up to two or more hours.

(A5 at col. 4:36-62; *see also* A45-A47.)

The specification thus explains that the claimed thixotropic composition must start at a particular setting viscosity, decrease to a shear viscosity when shaken, and then return to its setting viscosity upon immediate contact with the mucosal surfaces of the nasal cavity. Before application of shear, the composition is a gel that maintains the TAA particles suspended therein. The composition has this same viscosity in deposited form on the mucosal surfaces of the nasal cavities – upon immediate contact with the mucosal surfaces. Upon application of shear, the composition is a freely flowing liquid that, when sprayed, deposits on at least four specific portions of the nasal cavity: "the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses; and the turbinates which overlie the conchas of the nasal cavities." (A5 at col. 4:45-54.)

In another passage, the specification clearly and explicitly defines what those shear and setting viscosities must be, stating:

> For convenience, the viscosity of the composition at rest is referred to as the "setting viscosity" and the viscosity of the composition which is shaken is referred to as the "shear viscosity." The setting viscosity of the composition should be sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition and to retain for an extended

> period of time the composition on the mucosal surfaces on which it is deposited in the nasal cavities, that is, the composition resists being swept away by the mucocillary forces which are present in the nasal cavities. The shear viscosity of the composition is sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist.

(A5-A6 at cols. 4:63-5:9.) In other words, the claimed composition must exhibit two viscosities: (1) a "setting viscosity" both when the composition is at rest and when it deposits on the mucosal surfaces of the nasal cavity; and (2) a "shear viscosity" when the composition is subjected to shear or shaken. The setting viscosity allows the composition to be a gel that keeps the particles of TAA suspended and dispersed in the composition at rest and to be retained on the mucosal surfaces of the nasal cavity. The shear viscosity allows the composition to become a freely flowable liquid that when sprayed forms a fine mist that deposits on the target tissues or "desired mucosa": the anterior regions of the nose, the frontal and maxillary sinuses and the turbinates.

The specification also informs the person of skill in the art what it means for the composition to resist being cleared from the nasal cavity. The specification explains:

> [i]n order to remain in contact with the target tissues, the medicament must be capable of resisting those forces in the nasal passages that function to remove particles from the nose. Such forces, referred to as 'mucocillary clearance', are recognized as being extremely effective in removing particles from the nose in a rapid manner, for example, within 10-30 minutes from the time the particles enter the nose.

(A4 at col. 1:50-57.) Accordingly, the specification ties resistance to clearance from the mucosal surfaces to the timing for normal mucociliary clearance. The mucociliary forces would normally sweep a composition away within 10-30 minutes; therefore, a composition that resists those forces must remain for at least 30 minutes.

Notably, the specification repeatedly refers to "the" composition of the present invention and "the" thixotropic properties it exhibits, signaling that there is only one composition claimed and it has the specific listed thixotropic properties. For instance "*the* composition of *the present*

invention" contains an excipient that maintains the TAA particles in a "thixotropic suspension." (A5 at col. 4:28-31 (emphasis added).) Moreover, "*the* thixotropic nature of *the* composition at rest" is a gel; "*the* viscosity of *the* composition at rest" is relatively high; "as *the* composition is subjected to shear . . . *the* viscosity of the composition decreases . . ."; "[t]hus, *the* thixotropic composition is such that it comprises a freely flowable liquid . . ."; "in deposited and relatively unstressed form, *the* composition increases in viscosity"; and so on. (A5 at col. 4:31-59(emphasis added).) The repeated use of the word "the" to describe "the composition of the present invention" and its thixotropic properties is definitive. There is not even a hint that any other composition is claimed or that the composition may exhibit any other thixotropic properties. Rather, the composition must have the specific properties as described in the specification. *See, e.g., Honeywell Int'l Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1320 (Fed. Cir. 2006) (holding that, when the patent expressly describes the "present invention," the scope of the claim cannot be broadened beyond this description); *Microsoft*, 357 F.3d at 1348 ("In light of . . . clear statements in the specification that the invention ('the present system') is directed to communications 'over a standard telephone line,' we cannot read the claims . . . to encompass data transmission over a packet-switched network.").

Simply put, the applicant told the Patent Office and the world that this particular composition with these particular thixotropic properties is his invention. The public "is entitled to take [him] at his word." *Honeywell*, 452 F.3d at 1318.

2. The Prosecution Histories Confirm That The Applicant Limited The Claimed Composition To The Specific Thixotropic Properties Described In The Specification.

The prosecution histories confirm that Barr's proposed construction is correct. The prosecution history of the '573 patent is replete with statements demonstrating that the claimed

invention was not related to a generally thixotropic composition, but instead limited to the specific thixotropic properties recited in the claims and specification.[3]

First, the applicants represented to the Patent Office that "thixotropic" as recited in the claims means the specific thixotropic properties detailed in the specification. For example, when responding to the Examiner's rejection over prior art, the applicants stated:

> The composition is characterized by its having the ability to remain in contact with target tissues in the nasal cavities for relatively long periods of time, for example, at least about an hour. The ease with which the composition is sprayed into the nasal cavities and its ability to remain in contact with target tissues for relatively long periods of time are attributed to a suspending agent which imparts to the composition *thixotropic properties, as described in the present application on pages 9, 10 and 11. Applicant's claims include a definition of the thixotropic properties of the composition*."

(A100 (citing A45-A47) (emphasis added).) Pages 9-11 of the patent application track exactly the description of the thixotropic nature of the composition detailed in the specification. (*Compare* A45-A47 *with* A5-A6 at cols. 4:28-5:9.)

The applicant was even more emphatic in response to the Examiner's rejection on grounds of indefiniteness: "Claim 8 has been amended to define the gel-like form of the composition as having suspended therein the solid particles of medicament. The Examiner's attention is directed to the present application, pages 9 and 10, *wherein there is a detailed discussion of the composition and the thixotropic nature thereof*, including the nature of the freely flowable liquid form of the composition and its gel-like form." (A108 (citing A45-A47)

[3] The Federal Circuit has held that "the prosecution history of one patent is relevant to understanding the scope of a common term in a second patent stemming from the same parent application." *Microsoft*, 357 F.3d at 1349 (limiting scope of term based on disclaimer in prosecution history of sister patent). Where the "patents all derive from the same parent application and share many common terms, [the court] must interpret the claims consistently across all asserted patents." *NTP, Inc. v. Research In Motion, Ltd.*, 392 F.3d 1336, 1345-46 (Fed. Cir. 2004). The '329 patent is a continuation application of the '573 patent, and both contain identical specifications. Accordingly, representations made in the prosecution of the '573 patent are equally binding on Plaintiffs with respect to the claims of the '329 patent.

(emphasis added).) In other words, according to the applicant, the thixotropic nature of the claimed composition is not indefinite because it is defined in the patent specification.

Second, the prosecution history reveals that the prior art discloses general thixotropic properties but that the applicant asserted and convinced the Patent Office that the prior art does not disclose the specific thixotropic properties detailed in the patents. For instance, in response to an anticipation rejection based on two prior art articles describing clinical trials involving Nasacort® AQ, authored by Settipane and Kobayashi, the applicant distinguished those articles, arguing that "*[a]lthough these articles disclose a thixotropic aqueous intranasal formulation of triamcinolone acetonide* for use in treating allergic rhinitis, *the following claimed elements are not disclosed*: . . . a suspending agent for dispersing the solid particles of medicament and for imparting to the composition *the thixotropic properties which are defined in applicant's claims.*" (A101-A102 (emphasis added); A326, A334 (Settipane reference); A339, A347 (Kobayashi reference).)

In addition, it was known that other aqueous nasal sprays already on the market for treatment of allergic rhinitis exhibited general thixotropic behavior, and the applicants discussed this with the Patent Office: "The IDS filed on November 23, 1998 identified various prior art commercial compositions which are used to treat allergic rhinitis and which contain the same preferred suspending agent . . . used in the compositions of the present invention. As expected, applicant's recent tests on such prior art compositions have shown that such prior art compositions exhibit thixotropic properties." (A210-A211 (citing A193-A194).)

Subsequently, in explaining the reasons for allowance, the examiner made clear that he would allow the claims because he believed the specific "thixotropic" traits of the claimed invention were unique: "the conclusion [of allowance] was made by determining that the

claimed composition comprising *unique thixotropic properties*, with *specific viscosity traits* (sheared and/or unsheared), and further comprising triamcinolone acetonide as medicament was not explicitly taught or suggested by the prior art of record." (A215 (emphasis added).) *See Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1138-39 (Fed. Cir. 2003) (finding that examiner's statements supported limitation of claim term).

It is a bedrock principle of claim construction that "[c]laims may not be construed one way in order to obtain their allowance and in a different way against accused infringers." *Southwall*, 54 F.3d at 1576; *see also Microsoft*, 357 F.3d at 1349-51 (interpreting "sending," "transmitting," and "receiving" limitations as requiring transmission over telephone line when patentee stated during prosecution that invention transmits over a standard telephone line); *Springs Window Fashions*, 323 F.3d at 995 (patentee "must be held to the restrictive claim construction that was argued during prosecution").

The public notice function of the prosecution history requires that Plaintiffs be held to what the applicant declared was the scope of the thixotropic properties of his invention during prosecution. The public has a "right to rely" on statements as to the scope of the invention made in the prosecution history as well as the Examiner's reasons for allowing the claims. *See Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1347 (Fed. Cir. 1998); *see also Hockerson-Halberstadt, Inc. v. Avia Group, Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000) ("[The patentee's] argument therefore reduces to a request for a mulligan that would erase from the prosecution history the inventor's disavowal of a particular aspect of a claim term's meaning. . . . Were we to accept [the patentee's] position, we would undercut the public's reliance on a statement that was in the public record and upon which reasonable competitors formed their business strategies."); *Biogen*, 318 F.3d at 1138-39.

The prosecution history thus conclusively confirms that the definition of "thixotropic" in the specification governs the scope of the asserted patent claims.

3. Plaintiffs' Construction Of "Thixotropic" Improperly Ignores The Intrinsic Record In Favor Of A Definition From An Extrinsic Source.

While Barr's construction is derived from the intrinsic record, as required by controlling Federal Circuit precedent, Plaintiffs, in contrast, derive their construction from an extrinsic source at odds with the intrinsic record. Plaintiffs seek to define the term very broadly to cover any composition with a viscosity that decreases under shear, "followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed." (*See, e.g.*, D.I. 114, Joint Claim Chart, '573 patent at 2.) Plaintiffs cite neither the specification nor the prosecution history for their construction of the term. Indeed, the specification never mentions any "time-dependent recovery," and it certainly never suggests such a recovery can be "gradual." Ignoring the patent at issue, Plaintiffs instead use a definition derived from a textbook entitled "An Introduction to Rheology." The Federal Circuit has repeatedly held, however, that such an approach is improper: that the specification and prosecution history trump such contrary extrinsic evidence.

Moreover, after *Phillips*, it is clear that the Federal Circuit does not permit a broader construction of the claims than is disclosed in the specification and prosecution history. *See, e.g.*, *Nystrom*, 424 F.3d at 1142-43 (holding that the term "board" is limited to "wood cut from a log" because that is the only type of board described in the specification); *On Demand*, 442 F.3d at 1339-40 (limiting the term "customer" to a "retail customer" because that was how "customer" was disclosed in the specification). A long line of Federal Circuit cases – stretching before and after *Phillips* – have rejected expansive interpretations of broadly-worded claims where, as here, the specification creates a narrower meaning. *See, e.g.*, *Andersen Corp. v. Fiber Composites*,

LLC, 474 F.3d 1361, 1366, 1375 (Fed. Cir. 2007) (limiting scope of claim where specification implicitly defined the term more narrowly than ordinary meaning); *Honeywell*, 452 F.3d at 1319-20 (same); *Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004) (same); *Watts v. XL Sys.*, 232 F.3d 877, 882-83 (Fed. Cir. 2000) (same); *Wang Labs, Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1382-83 (Fed. Cir. 1999) (same); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1300-01 (Fed. Cir. 1999) (same); *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1298 (Fed. Cir. 1999) (same); *O.I. Corp.*, 115 F.3d at 1581 (same).

Not only does Plaintiffs' general definition of "thixotropic" fail to address the specific viscosities recited the patents, it is also inconsistent with the applicant's recitation of the invention. The applicant made it very clear that the invention allows the composition to remain in place once sprayed and resist clearance by mucociliary forces, which the patent describes as "extremely effective in removing particles from the nose in a rapid manner, for example, within 10-30 minutes from the time the particles enter the nose." (A4 at col. 1:54-57.) Resistance to such "extremely effective" and "rapid" forces is not compatible with Plaintiffs' proposed "gradual" increase in viscosity.

It violates Federal Circuit precedent and the notice function of patents to define "thixotropic" based on extrinsic evidence in a manner incompatible with the specification and prosecution history, as Plaintiffs seek to do here. Under *Phillips* and its progeny, the patentee "is not entitled to a claim construction divorced from the context of the written description and prosecution history." *Nystrom*, 424 F.3d at 1144-45. Because the applicants consistently and clearly stated that the invention was limited to the specific thixotropic properties detailed in the specification and claims, the term should be construed accordingly. It should not be construed

according to contrary extrinsic evidence. Once the proper methodology is applied, it is clear that Barr's construction is the correct one.

B. The "Thixotropic" Composition In Claim 34 Of The '573 Patent And Claims 13, 14, And 25 Of The '329 Patent Is Limited To The Thixotropic Properties Set Forth In The Specification.

Independent claim 34 of the '573 patent and independent claims 13, 14, and 25 of the '329 patent all claim a "thixotropic" composition or composition with "thixotropic properties." The term "thixotropic" in these claims should be construed as discussed above, with one caveat. Claim 34 of the '573 patent further specifies that the composition must be "retained on each of [the mucosal surfaces of the nasal cavity] for at least about an hour."[4] Thus, this claim is limited to a composition that resists mucociliary clearance for at least 60 minutes, rather than just 30 minutes.

C. Claim 1 Of The '573 Patent And Claim 6 Of The '329 Patent Recite Specific Claimed Thixotropic Properties.

Both independent claim 1 of the '573 patent and independent claim 6 of the '329 patent recite specific thixotropic properties that the claimed composition must demonstrate. Both require:

> a suspending agent in an amount effective to maintain said particles dispersed uniformly in the composition and to impart to the composition the following **thixotropic properties**:
> (i) the viscosity of the composition in unsheared form is **relatively high**, with the composition being a **gel** having said particles suspended therein;
> (ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes **relatively low** and such that the composition in the form of a mist flows readily into the nasal passages for deposit on **the mucosal surfaces of the nasal cavity**; and
> (iii) **in deposited form on the mucosal surfaces**, the viscosity of the composition is **relatively high** and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity

[4] Several dependent claims also contain this limitation or something substantially similar. (A10-A11 at cols. 14:45-67, 15:4-19; A21 at col. 14:53-55.)

(A9-A10 at cols. 12:65-13:12; A21 at col. 13:43-59 (emphasis added).)

1. In Its Original State, The Composition Is A Gel With A "Relatively High" Setting Viscosity: "Relatively High" Should Be Accorded Its Ordinary Meaning.

The claims recite that the setting viscosity of the composition before it is shaken is "relatively high" with "the composition being a gel having said particles suspended therein." The parties' construe this clause of the claims, clause (i), as follows:

Claim Limitation	Barr's Construction	Plaintiffs' Construction
(i) the viscosity of the composition in unsheared form is **relatively high**, with the composition being a **gel** having said particles suspended therein	At rest the composition is a gel with a setting viscosity (or, viscosity at rest) that is higher than the shear viscosity and sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition.	The viscosity of the composition at rest during non-use is sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition. "Relatively high" viscosities range from about 400 to about 1000 cps when measured by the method disclosed in the specification.

For the most part, both parties take their constructions of clause (i) from the specification's definition of setting viscosity. (A5-A6 at cols. 4:36-39, 4:66-5:6.) The disparity arises in the very different constructions of clause (i)'s term "relatively high," and the failure of Plaintiffs to include the claim term "gel" in its definition. Barr contends that the term "relatively high" should be assigned its ordinary meaning. Plaintiffs incorrectly seek to restrict the term to a specific embodiment.

The proper construction of the term "relatively high" is "higher than the shear viscosity." This is both the ordinary meaning of the term and the definition advanced by the applicant during the prosecution of the patents. The specification of the patents does not define the term "relatively high." Rather, it simply associates that term with the setting viscosity or viscosity at

rest of the composition, explaining that "[t]he viscosity of the composition at rest is relatively high, *for example*, about 400 to about 1000 cp." (A5 at col. 4:39-41 (emphasis added).)

The term "relatively" appears in the specification only when preceding the term "high" or "low." It is not otherwise defined or explained. In particular, the specification does not expressly or implicitly "reveal a special definition" for "relatively" "that differs from the meaning it would otherwise possess." *Phillips*, 415 F.3d at 1316. When claim construction involves "application of the widely accepted meaning of commonly understood words," general purpose dictionaries may assist the determination of a term's ordinary meaning. *Id.* at 1314. "Relatively" means "in a relative manner; in relation to or compared with something else; not absolutely." (A355.)

Significantly, to secure allowance of the claims, the applicants confirmed that the term "relatively" in the context of the invention is defined in accordance with its ordinary meaning. During the prosecution of the '573 patent, the Patent Office rejected the claims under 35 U.S.C. § 112 for indefiniteness for failing to particularly point and out and distinctly claim the subject matter that applicant regards as the invention. (A82.) The examiner found the pertinent claim "vague and indefinite in its recitation of 'bodily condition', 'relatively', and 'gel-like', the metes and bounds of cited terminologies are not defined." (*Id.*) The applicants responded: "[w]ith respect to the Examiner's comments on the term 'relatively', this term is used *in its normal way* to compare qualitatively the composition in its 'high' viscosity form with the composition in its 'low' viscosity form." (A108 (emphasis added).) Accordingly, the applicants made it clear that the term "relatively high" simply means that the viscosity is higher than when it is in its lower, i.e., shear, viscosity. This is entirely consistent with the ordinary meaning of the term.

Contrary to well established rules of claim construction, Plaintiffs urge this Court to artificially confine the term "relatively high" to a specific example described in the patent's text. According to Plaintiffs, "'[r]elatively high' viscosities range from about 400 to about 1000 cps when measured by the method disclosed in the specification." (*See, e.g.*, D.I. 114, Joint Claim Chart, '573 patent at 2-3.) This proposed construction ignores the plain and ordinary meaning of the claim language and is contrary to the specification and prosecution history.

Plaintiffs cite two portions of the specification to support its definition, both of which make it clear that the numerical ranges are simply an embodiment. First, Plaintiffs cite the following passage: "The viscosity of the composition at rest is relatively high, for example, about 400 to about 1000 cp." (A5 at col. 4:39-41.) The use of the term "for example" makes it clear that this numerical range is simply an embodiment, however. It is not intended to define the term "relatively high." The second passage cited to by Plaintiffs suffers the same infirmity: "*[b]y way of example*, a setting viscosity of about 400 to about 800 cp is recommended for a composition containing an anti-inflammatory steroid, for example, triamcinolone acetonide." (A6 at col. 5:14-17 (emphasis added).) The patents could not be clearer that the numerical range for the setting viscosity is an embodiment. "By way of example" and "for example" make that abundantly clear. Moreover, when the applicants wanted to limit the setting viscosity to a numerical range, they did exactly that by explicitly setting forth that range in the claims. (*See, e.g.*, A10 at col. 13:20-46; A21 at col. 13:2-25.)

As the *en banc* Federal Circuit has explained, "the specification often describes very specific embodiments of the invention, [but] we have repeatedly warned against confining the claims to those embodiments." *Phillips*, 415 F.3d at 1323 (citing *Nazomi Communications, Inc. v. ARM Holdings, PLC*, 403 F.3d 1364, 1369 (Fed. Cir. 2005)). "[T]he purpose[] of the

specification [is] to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so." *Phillips*, 415 F.3d at 1323. One of the best ways to provide such teaching of how to practice the invention is to provide an example. *Id*. The patent, however, should not be limited to that example and limitations relating to the preferred embodiment should not be read into the claims from the specification absent some evidence that such a limitation was intended. *Id*. There is no such evidence here. Indeed, the evidence compels the opposite conclusion – the applicant clearly defined the term "relatively" according to its ordinary meaning. Plaintiffs' construction, therefore, violates binding Federal Circuit precedent: "In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Id*.

Finally, Plaintiffs' construction of clause (i) suffers from another fundamental flaw. Plaintiffs completely write the word "gel" out of this portion of the claims. Again, this directly conflicts with controlling Federal Circuit precedent and should be rejected. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (rejecting patentee's construction because to do so would render terms meaningless and read limitations out of the claim: "claims are interpreted with an eye toward giving effect to all terms in the claim"); *Pause Technology, LLC v. TiVo, Inc.*, 419 F.3d 1326, 1334 (Fed. Cir. 2005) ("Pause attaches no significance to the word 'predetermine.' In construing claims, however, we must give each claim term the respect that it is due.").

2. In Its Shear State, The Viscosity Of The Composition Becomes "Relatively Low" With A Shear Viscosity That Allows It To Reach Each Of The Mucosal Surfaces Of The Nasal Cavity: "Relatively Low" Should Be Accorded Its Ordinary Meaning.

In clause (ii) of '573 patent claim 1 and '329 patent claim 6, the composition decreases to its shear viscosity. The parties define clause (ii) as follows:

Claim Limitation	Barr's Construction	Plaintiffs' Construction
(ii) the viscosity of the composition becomes **relatively low** and such that the composition in the form of a mist flows readily into the nasal passages for deposit on **the mucosal surfaces of the nasal cavity**	As the composition is shaken, the composition has a shear viscosity (or, viscosity when shaken) that becomes lower than the setting viscosity and becomes sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity.	Upon application of shear force such as shaking, the viscosity of the composition decreases sufficiently to allow the composition to flow freely through a pump orifice and break up into a fine mist that can infiltrate and deposit on mucosal regions. "Relatively low" viscosities range from about 50 to about 200 cps when measured by the method disclosed in the specification.

A primary dispute here appears to center on the definition of "relatively low."[5] Similar to "relatively high," the term "relatively low" should be construed consistent with its ordinary meaning of "lower than the setting viscosity." Like "relatively high," this construction is consistent with the definition advanced by the applicant during prosecution of the patents. (*See supra* at p. 21.) The specification never defines the term "relatively low." Indeed, "relatively low" only appears in the specification when a description of the invention mirroring the claims is set forth. (*See, e.g.*, A4 at col. 2:27-38.) And, again, the applicants put the PATENT OFFICE and public on notice as to the construction of the term when stating during the prosecution that "[w]ith respect to the Examiner's comments on the term 'relatively', this term is used *in its*

[5] The parties also dispute the meaning of the term "the mucosal surfaces of the nasal cavity," which is addressed separately below.

normal way to compare qualitatively the composition in its 'high' viscosity form with the composition in its 'low' viscosity form." (A108 (emphasis added).) Accordingly, the applicants made it clear that the term "relatively low" simply means that the viscosity is lower than when it is in its high, *i.e.*, setting, viscosity.

Plaintiffs again advocate improperly importing the preferred embodiment as a limitation into the claim, arguing that "'[r]elatively low' viscosities range from about 50 to about 200 cps when measured by the method disclosed in the specification." (*See, e.g.*, D.I. 114, Joint Claim Chart, '573 patent at 3.) Plaintiffs cite to two portions of the specification – the same two passages Plaintiffs cite for their construction of "relatively high." The second passage includes the statement: "*A recommended* shear viscosity for such a composition is about 50 to about 200 cp." (A6 at col. 5:17-18 (emphasis added).) Not only does that sentence not even use the term "relatively low" but it is clearly just a preferred embodiment of the shear viscosity. Similarly, uncited by Plaintiffs, another part of the specification clearly marks the numerical range as a preferred embodiment: "the viscosity of the composition decreases (*for example*, to about 50 to about 200 cp) . . . ." (A5 at col. 4:43-45 (emphasis added).) Plaintiffs' construction of "relatively low" is plainly incorrect. *See Phillips*, 415 F.3d at 1323. This Court should apply the ordinary meaning to the term "relatively low" – the same definition advocated by the applicants during the prosecution of the '573 patent.

3. When Deposited In The Nasal Cavity, The Composition Must Have Returned To Its Setting Viscosity In Order To Perform Its Intended Purpose.

The parties construe clause (iii) of '573 patent claim 1 and '329 patent claim 6 as follows:

Claim Limitation	Barr's Construction	Plaintiffs' Construction
(iii) **in deposited form on the mucosal surfaces**, the viscosity	Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting	Upon cessation of shear force and in relatively unstressed form following deposition on mucosal

of the composition **is relatively high** and such that it **resists being cleared from the mucosal surfaces by the inherent mucocillary forces** which are present in the nasal cavity	viscosity (or viscosity at rest). That setting viscosity is sufficiently high to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity, i.e., the composition resists being swept away by the mucociliary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes.	surfaces, the viscosity of the composition increases to a relatively high value such that the composition is retained on the mucosal surfaces on which it is deposited and resists being swept away by mucocillary forces, and reverts to the viscosity in unsheared form.

There should be no dispute as what clause (iii) of '573 patent claim 1 and '329 patent claim 6 means. The specification very clearly defines the "setting viscosity" as "sufficiently high to . . . retain for an extended period of time the composition on the mucosal surfaces on which it is deposited in the nasal cavities, that is, the composition resists being swept away by the mucocillary forces which are present in the nasal cavities." (A5-A6 at cols. 4:66-5:6.) In deposited form, the composition is the same gel with the same viscosity as its viscosity at rest before application of shear as described in clause (i), and is sufficient to resist mucociliary forces for at least 30 minutes.

a. The Patents Make It Clear That The Viscosity Must Return To Its Original Setting Viscosity In Deposited Form.

The patents make it very clear that there are only two viscosities, not three – the setting viscosity and the shear viscosity. The composition begins at its setting viscosity, becomes the shear viscosity after shaken, and then returns to its original setting viscosity when deposited on the mucosal surfaces of the nasal cavity. There is no discussion anywhere in the patent specification or prosecution history of any third viscosity that the composition takes when deposited on the mucosal surfaces of the nasal cavity. Rather, the specification makes it clear that the viscosity when deposited is the same setting viscosity the composition exhibits before shaking:

> For convenience, the viscosity of the composition at rest is referred to as the 'setting viscosity' and the viscosity of the composition which is shaken is referred to as the 'shear viscosity'. As mentioned above, the *setting viscosity* of the composition should be sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition *and* to retain for an extended period of time the composition on the mucosal surfaces on which it is deposited in the nasal cavities, that is, the composition resists being swept away by the mucocillary forces which are present in the nasal cavities. The *shear viscosity* of the composition is sufficiently low to permit the composition to flow freely through the pump orifice and to break up into a fine mist.

(A5-A6 at cols. 4:63-5:9 (emphasis added).)

Moreover, the claims use the same term, "relatively high," to describe the viscosity of the composition both before shear is applied in clause (i), and in deposited form in the nasal cavity in clause (iii). The Federal Circuit has repeatedly stated that courts "are obliged to construe [a] term [ ] consistently throughout the claims." *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1159 (Fed. Cir. 1997); *Digital Biometrics*, 149 F.3d at 1345 ("[T]he same word appearing in the same claim should be interpreted consistently.").

Plaintiffs do not clearly disagree with Barr that the viscosity of the composition when deposited on the mucosal surfaces is the same as the viscosity at rest, before shear is applied.[6] But to the extent Plaintiffs advocate a construction of "relatively high" for clause (iii) that differs from the construction in clause (i), or suggest that there is some third viscosity of the composition that is evidenced nowhere in the intrinsic record, their construction is plainly wrong. Accordingly, clause (iii) must be construed to require the composition to return to the same setting viscosity the composition has at rest, before shear is applied.

[6] Plaintiffs do note in their proffered construction of claims 1 and 6 that the viscosity "*reverts* to the viscosity in unsheared form." (D.I. 114, Joint Claim Chart, '573 patent at 3; Joint Claim Chart, '329 patent at 5.)

b. The Return To Setting Viscosity Must Be Immediate.

A central dispute regarding clause (iii) of the claims, as well as all of the claims containing the claim term "thixotropic," appears to turn on *when* the composition must return to the setting viscosity. The proper construction requires that the composition exhibit the setting viscosity upon being deposited on the mucosal surfaces of the nasal cavity. This is required by the language of the claims and by the specification.

Claim 1 of the '573 patent and Claim 6 of the '329 patent recite that "*in deposited form* on the mucosal surfaces, the viscosity of the composition *is* relatively high and *such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces* which are present in the nasal cavity." (A10 at col. 13:8-12; A21 at col. 13:54-59.) By their plain language, the claims require that, when it is deposited, the composition must have returned to its setting viscosity.[7]

Tellingly, the claims and specification never discuss an allotment of time for the viscosity to increase following deposit on the mucosal surfaces of the nasal cavity. To the contrary, the claims clearly state that the composition "is" in its setting viscosity "in deposited form." Furthermore, the claims require the viscosity in deposited form be "such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity." The specification details how mucociliary forces in the nasal passages function to remove particles from the nose:

> the medicament should remain in contact with the target tissues for relatively long periods of time. . . . In order to remain in contact with the target tissues, the medicament must be capable of resisting those forces in the nasal passages that function to remove particles from the nose. Such forces, referred to as 'mucocillary clearance', are recognized as being *extremely effective* in removing

[7] This requirement applies equally to claim 34 of the '573 patent and claims 13, 14 and 25 of the '329 patent based on the proper construction of "thixotropic".

> particles from the nose in a *rapid* manner, for example, within 10-30 minutes from the time the particles enter the nose.

(A4 at col. 1:46-57 (emphasis added).) In order to resist those mucociliary forces, the composition must have already reached its setting viscosity. If it only "gradually increases" to the setting viscosity, as Plaintiffs submit, then the composition will have already been swept away by the "extremely effective" and "rapid" mucociliary forces to another region of the body where the medicament cannot perform its nasal function by the time it has returned to its setting viscosity. Yet the specification provides that, "[i]n accordance with the present invention, the medicament remains in contact with the target tissues for relatively long periods of time, for example, at least about an hour and for even two or more hours." (A5 at col. 3:22-26.)

Moreover, the significance of the applicant's choice of the word "is" in clauses (i) and (iii) cannot be ignored, particularly when compared to the claims' discussion of the shear viscosity. The applicant claimed a composition whereby "(i) the viscosity of the composition in unsheared form ***is*** relatively high, . . . (ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition ***becomes*** relatively low . . . and (iii) in deposited form on the mucosal surfaces, the viscosity of the composition ***is*** relatively high . . . ." (A10 at col. 13:1-10; A21 at col. 13:46-56 (emphasis added).) The applicant's use of the term "becomes" for when the composition is shaken plainly allows for some time for the viscosity to lower. In stark contrast, the applicant deliberately chose to use the term "is" and not "becomes" for when the composition is relatively high in deposited form, thus according no time for the viscosity to increase once it has deposited on the mucosal surfaces. The viscosity must already be relatively high once it is deposited.

With no allowance for time for the composition to increase to its setting viscosity in the claims, specification, or prosecution history, the construction is clear: the composition must have already achieved that setting viscosity "in deposited form."

c. The Composition Must Resist Being Cleared From The Mucosal Surfaces For At Least 30 Minutes.

The specification fails to explicitly define what is meant by "resists being cleared." But, as discussed above in relation to the definition of "thixotropic" (*supra* at p. 12), the specification states:

> [i]n order to remain in contact with the target tissues, the medicament must be capable of resisting those forces in the nasal passages that function to remove particles from the nose. Such forces, referred to as 'mucocillary clearance', are recognized as being extremely effective in removing particles from the nose in a rapid manner, for example, within 10-30 minutes from the time the particles enter the nose.

(A4 at col. 1:54-57.) Accordingly, the specification makes it clear that a composition that resists mucociliary forces must remain on the mucosal surfaces of the nasal cavity for at least 30 minutes.

D. Claims 5 And 35 Of The '573 Patent And Claims 1 And 26 Of The '329 Patent Explicitly Set Forth Numeric Thixotropic Properties.

Independent claim 5 of the '573 patent and independent claim 6 of the '329 patent further limit the thixotropic properties of the claimed composition, reciting numerical values for the viscosities that the claimed composition must demonstrate. Both recite:

> the amount of suspending agent being effective to maintain said solid particles dispersed uniformly in the composition and to impart to the composition the following **thixotropic properties**:
> (i) the viscosity of the composition in unsheared form is **about 400 to about 800 centipoise** [cp];
> (ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition is **about 50 to about 200 centipoise** [cp] and such that the composition in the form of a mist flows readily into the nasal passages for deposit **on the mucosal surfaces of the nasal cavity**; and

> (iii) in deposited form on the mucosal surfaces, the viscosity of the composition is **about 400 to about 800 centipoise** [cp] and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity

(A10 at col. 13:30-43; A21 at col. 13:11-25 (emphasis added).) In addition, dependent claim 26 of the '329 patent and dependent claim 35 of the '573 patent require that the viscosity of the composition in unsheared form be "about 400 to about 800 [or 1000] centipoise" and the shear viscosity be "about 50 to about 200 centipoise." (A11 at col. 16:21-24; A22 at col. 16:7-11.)

As for the initial viscosity, the proper construction is that the composition has a setting viscosity that is approximately 400 to approximately 800 or 1000 centipoise under certain testing conditions. The testing conditions are partially set forth in the specification. (*See, e.g.*, A6 at col. 5:18-21 ("Viscosity is measured using a Brookfield Synchro-Letric viscometer (Model LVT). The viscosity is measured at 20° C. The setting viscosity is measured after mixing at 30 rpm for 30 seconds.").) The specification does not provide any guidance as to the meaning of the term "about;" therefore, "approximately" is the appropriate definition. *See Merck & Co. v. Teva Pharm., USA, Inc.*, 395 F.3d 1364, 1369-70 (Fed. Cir. 2005) (holding that the plain meaning of "about" is "approximately" with no further limitations). Plaintiffs' definition does not appear to substantively deviate from that of Barr.

Turning to the shear viscosity, the proper construction is that the composition has a shear viscosity that is approximately 50 to approximately 200 cp under certain testing conditions, and is sufficiently low to permit to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. The testing conditions, again, are partially set forth in the specification. (A6 at col. 5:18-24.) Other than specifying a numerical range for the shear viscosity rather than deeming it "relatively low," these claims recite the same language for the

shear viscosity as those discussed above. (*See supra* at pp. 24-25.) Thus, Barr's proposed construction for these terms and arguments in support thereof are the same as in claim 1 of the '573 patent and claim 6 of the '329 patent. (*Id.*)

Finally, with respect to the composition in deposited form on the mucosal surfaces, the only way that these claims differ from claim 1 of the '573 patent and claim 6 of the '329 patent as discussed above is that "relatively high" has been replaced with the numerical range of "about 400 centipoise to about 800 [or about 1000] centipoise." Accordingly, except for "relatively high," Barr's proposed construction for this clause and arguments in support thereof are the same as advanced for claim 1 of the '573 patent and claim 6 of the '329 patent. (*See supra* at pp. 25-30.) The composition must return to its original setting viscosity upon immediate contact with the mucosal surfaces of the nasal cavity and must resist mucociliary clearance for at least 30 minutes. (*Id.*) As for the numerical viscosity ranges, Barr again proffers that "about" is properly defined as "approximately." There are no testing conditions in existence that can determine the viscosity of the composition in the nasal cavity.

III. When Sprayed, The Composition Must Deposit On Each Of The Mucosal Surfaces Of The Nasal Cavity.

The term "the mucosal surfaces of the nasal cavity" appears in independent claims 1 and 5 of the '573 patent and independent claims 1, 6, and 14 of the '329 patent. In addition, it forms part of the construction of "thixotropic" in claim 13 of the '329 patent. Here are the parties' proposed constructions:

Claim Limitation	Barr's Construction	Plaintiffs' Construction
The mucosal surfaces of the nasal cavities	The mucosal surfaces of the nasal cavity are the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses.	"Mucosal surfaces" are bodily tissues which line the nasal cavity. The "nasal cavity" includes, among other things, the anterior regions of the nose (frontal nasal

		cavities); the frontal sinus; the maxillary sinuses, and the turbinates which overlie the conchas of the nasal cavities.

There does not appear to be a substantive difference in the parties' construction of what constitutes the mucosal surfaces of the nasal cavity, as set forth in these patents. Barr avers that the mucosal surfaces of the nasal cavity are the mucous membranes that line, among other things: (1) the anterior regions of the nose, (2) the turbinates, (3) the maxillary sinuses, and (4) the frontal sinuses. That construction is supported by the specification. (A4-A5, A9 at cols. 1:5-10, 41-47, 2:47-63, 4:41-53, 11:15-18.) Plaintiffs do not appear to take a position at odds with that definition.

Rather, the primary difference arises from the application of the term within some of the claims. According to the language of the claims and based on the specification and prosecution history, the composition must reach and deposit on each of the four specifically identified mucosal surfaces of the nasal cavity: the anterior regions of the nose, the turbinates and the maxillary and frontal sinuses. By contrast, Plaintiffs' construction suggests that the composition may deposit on some, if any at all, regions.[8] The following portions of the parties' constructions of claim 1 of the '573 patent illustrate the divergence:

[8] Both parties agree that for claims 21 and 34 of the '573 patent (and dependent claims) the composition must deposit on "each of the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses, and on each of the mucosal surfaces which overlie the turbinates covering the conchas," as recited in those claims. (*See* D.I. 114, Joint Claim Chart, '573 patent at 8-9, 13.) It is not clear if Plaintiffs agree that claim 25 of the '329 patent (and its dependent claim) also contain this requirement. (*See* D.I. 114, Joint Claim Chart, '329 patent at 12-14.) To the extent they disagree, their construction is contrary to the plain language of the claim. In addition, Barr refers to the argument in this section.

Claim Limitation	Barr's Construction	Plaintiffs' Construction
(ii) the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for **deposit on the mucosal surfaces of the nasal cavity**	"…fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity…"	"…break up into a fine mist that can infiltrate and deposit on mucosal regions…"[9]
(iii) **in deposited form on the mucosal surfaces**, the viscosity of the composition is relatively high and such that it **resists being cleared from the mucosal surfaces** by the inherent mucocillary forces which are present in the nasal cavity	"Upon immediate contact with the mucosal surfaces,…retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity"	Upon cessation of shear force and in relatively unstressed form following deposition on mucosal surfaces …the composition is retained on the mucosal surfaces on which it is deposited…"

The language of the claims themselves confirms that Barr's construction is the proper one. The claims always preface "mucosal surfaces of the nasal cavity" with "the," not "some of the" or "at least one." And the mucosal surfaces are the mucous membranes that line, among other things, "the anterior regions of the nose (frontal nasal cavities); the frontal sinus; the maxillary sinuses; and the turbinates." (A5 at col. 4:47-51.) Plaintiffs simply read out the word "the" from the claim. Plaintiffs' definition is therefore improper for failure to give meaning to the full text of the claim. *See Bicon*, 441 F.3d at 950; *Pause Technology*, 419 F.3d at 1334.

Moreover, Plaintiffs improperly read in the language "on which it is deposited" into clause (iii) of the claims. The clause recites that, because of the composition's viscosity, it "resists being cleared from *the* mucosal surfaces;" yet Plaintiffs import the language "on which it is deposited." There is nothing in the claims themselves or the intrinsic record that authorizes

[9] While Plaintiffs use "mucosal regions" in claim 1 of the '573 patent and claim 6 of the '329 patent, they inexplicably substitute "mucosal surfaces" in claim 5 of the '573 patent and claim 1 of the '329 patent. Moreover, Plaintiffs do not indicate in their construction of claim 14 of the '329 patent whether the mist reaches "mucosal surfaces" or "the mucosal surfaces." (D.I. 114, Joint Claim Chart, '329 patent at 9-10.)

this alteration of the claim language. To the contrary, the specification provides the context for the meaning of this term within the claim and demonstrates that the composition must reach and remain on *each* of the four specifically identified mucosal surfaces.

Indeed, depositing on each of these mucosal surfaces is an asserted benefit of the invention. In explaining what constitutes the patent's invention, the specification states that "this invention relates to an aqueous composition containing a medicament that is effective in treating an abnormal bodily condition by virtue of its being present on the surfaces of the mucosa which line the nasal cavities." (A4 at col. 1:5-10 (medicament "is effective in treating allergic rhinitis by virtue of its being present on the mucosal surfaces of the nasal cavity").) The specification provides that "the present invention provides means for delivering a medicament readily *to the many portions of the nasal cavities* where it can perform its pharmacological function. In accordance with the present invention, the medicament remains in contact with *the target tissues* for relatively long periods of time, for example, at least about an hour and for even two or more hours." (A5 at col. 3:19-26 (emphasis added).) The specification states the medicament reaches "*the many* portions of the nasal cavity," not one or some of the many portions of the nasal cavity, and that it "remains in contact with *the* target tissues," not one or some of the target tissues. Moreover, in the definition of "thixotropic," the specification makes clear that the composition of the invention, when sheared, is sufficiently liquid form a mist that "deposits on *at least* the following parts of the nose: the anterior regions of the nose . . .; the frontal sinus; the maxillary sinuses; and the turbinates . . . . Thus, the thixotropic composition is such that it comprises a freely flowable liquid, and in sprayed form a fine mist that *finds its way to and deposits on the desired mucosa*." (A5 at col. 4:47-53 (emphasis added).)

The specification also recites that "the nature of the pharmaceutical composition containing the medicament should be such that the medicament is delivered readily to *all portions of the nasal cavities (the target tissues)* where it performs its pharmacological function. In addition, the medicament should remain in contact with the target tissues for relatively long periods of time." (A4 at col. 1:41-47 (emphasis added).) Later, when discussing tests purportedly showing where the claimed composition actually deposits, the specification lists the target tissues: "Included in the regions of interest are the following target sites: the frontal cavities [i.e., the anterior regions of the nose], frontal sinus, maxillary sinuses, superior concha and inferior concha [i.e., the turbinates]." (A9 at col. 11:15-18.)

In addition, the prosecution history supports Barr's construction of the limitation. In response to a Patent Office rejection based on anticipation of the claims by the Settipane and Kobayashi references, the applicants stated that "neither of the articles discloses the claim elements regarding the *specific areas of the nasal cavity where the medicament is deposited* and the amount of time that the medicament is retained on the mucosal surfaces." (A103 (emphasis added) (citing A325-A337 (Settipane reference); A338-A350 (Kobayashi reference)).) The applicant thus made it clear that the composition has the ability to reach a sufficiently low shear viscosity to deposit on the four identified mucosal surfaces, which is an important feature of the invention. Moreover, the Patent Office noted that "according to applicant's disclosure thixotropic properties entails effective amount of medicant [*sic*] to be deposited in various sections of the nasal passage." (A114.) Thus, the Patent Office also understood that the deposit of the composition on each of the mucosal surfaces was a significant feature of the alleged invention.

The language of the claims, the specification, and prosecution history all confirm that the composition must deposit and remain on each of the four specifically identified mucosal surfaces: the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses.

IV. "Aqueous Pharmaceutical Composition" Should Be Accorded Its Ordinary Meaning.

The term "aqueous pharmaceutical composition" appears in each of the asserted claims of the patents. Here are the parties' proposed constructions of this term:

Claim Term	Barr's Construction	Plaintiffs' Construction
aqueous pharmaceutical composition	A water-based combination of ingredients that includes a medicament	A water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation

Barr's construction comports with the plain and ordinary meaning of the words "aqueous," "pharmaceutical," and "composition." Plaintiffs' construction does not. Plaintiffs do not appear to dispute that "aqueous" means "water-based" as mentioned in the specification. (A5 at col. 3:45.) They also do not appear to dispute that a "composition" is a combination of ingredients. Through the term "pharmaceutical," however, Plaintiffs want to impose a multitude of requirements that are not warranted by either the ordinary meaning of the word "pharmaceutical" or anything in the intrinsic record.

The term "pharmaceutical" simply means "of or by drugs." (A354.)[10] Thus, a "pharmaceutical" composition is a composition that contains a drug, or "medicament" in the

[10] (*See also* A359 ("pharmaceutical[:] . . . *adj.* . . . of, relating to, or engaged in pharmacy or the manufacture and sale of pharmaceuticals. . . . *n.* . . . a medicinal drug"; "pharmacy[:] . . . *n.* . . . the art or practice of preparing, preserving, compounding and dispensing drugs"); A362 (same).)

terminology of the specification. *See Phillips*, 415 F.3d 1314 ("In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful."); *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001) (holding that plain reading of claim terms did not require "elaborate interpretation").

Plaintiffs seek to import a host of additional requirements into the term "pharmaceutical" – namely, that the composition must contain additional ingredients that are "compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation." (*See, e.g.*, D.I. 114, Joint Claim Chart, '573 patent at 1.) Plaintiffs attempt to support this extensive definition of the term "pharmaceutical" by reference to a single portion of the specification. (*See* A5 at col. 3:45-54.) But nowhere does the specification suggest, let alone conclusively establish, a definition of the phrase "aqueous pharmaceutical composition" different than the ordinary meaning. Indeed, the section cited by Plaintiffs merely provides a general description of the alleged invention and what things may be included in the "aqueous pharmaceutical composition." Neither this section nor anything else in the specification clearly shows that the patentee acted as his own lexicographer and departed from the ordinary meaning of the term "pharmaceutical." *Brown*, 265 F.3d at 1352 (holding that there was no basis in the specification for altering the plain meaning of the disputed claim term); *see also CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005) (explaining that patent applicant may alter scope of claim limitation from ordinary meaning if he "*consistently and clearly* use[s] a term in a manner either more or less expansive than its general usage in the relevant community") (emphasis added).

"Aqueous pharmaceutical composition" should thus be construed according to its ordinary meaning and should not include the additional limitations Plaintiffs seek to add.

V. "Pharmaceutically Effective Amount" Should Be Accorded Its Ordinary Meaning.

The term "pharmaceutically effective amount" appears in independent claims 1 and 34 of the '573 patent and independent claims 6 and 14 of the '329 patent. Here are the parties' proposed constructions of this term:

Claim Term	Barr's Construction	Plaintiffs' Construction
pharmaceutically effective amount	An amount that exerts pharmacological action and provides relief of nasal symptoms cause by the abnormal bodily condition	One that exerts the pharmacological action of the medicament

The plain and ordinary meaning of "pharmaceutically effective amount" is an amount that produces the intended pharmaceutical result. (*See* A353 ("effective: . . . having an effect; . . . producing a definite or desired result.").) The patent explains that the intended pharmaceutical result of the application of TAA in the claimed composition to the nasal cavities is to treat an abnormal bodily condition of the nasal cavities. Allergic rhinitis is an example. (*See* A5 at col. 3:59-67.) The TAA treats the condition by "provid[ing] the relief of nasal symptoms" caused by the abnormal bodily condition. (A5 at col. 3:65-67.)

Plaintiffs' construction is limited to "exerts pharmacological action," which adds nothing to the definition of "pharmaceutically effective." Indeed, it detracts from the definition; merely exerting pharmacological action does not make the TAA "pharmaceutically *effective*." To be effective, the medicament must do what it was intended to do – for TAA, to relieve the nasal symptoms caused by the abnormal bodily condition. Accordingly, Barr's construction, not Plaintiffs', is correct.

CONCLUSION

For these reasons, Plaintiffs' proposed claim constructions should be denied and the Court should adopt Barr's construction of the relevant claim terms described above.

September 10, 2007

YOUNG CONAWAY STARGATT & TAYLOR LLP

/s/ Karen L. Pascale

Josy W. Ingersoll (No. 1088) [jingersoll@ycst.com]
Karen L. Pascale (No. 2903) [kpascale@ycst.com]
Karen E. Keller (No. 4489) [kkeller@ycst.com]
The Brandywine Building
1000 West St., 17th Floor
P.O. Box 391
Wilmington, Delaware 19899-0391
Telephone: 302-571-6600
Fax: 302-571-1253

WINSTON & STRAWN LLP
George C. Lombardi
Maureen L. Rurka
Julia M. Mano
35 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 558-5600
Fax: (312) 558-5700

STERNE KESSLER GOLDSTEIN & FOX PLLC
Robert C. Millonig
Eldora L. Ellison
Laura A. Vogel
1100 New York Avenue, NW
Washington, D.C. 20005

Attorneys for Defendant, Barr Laboratories, Inc.

CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on September 10, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Steven J. Balick, Esquire [sbalick@ashby-geddes.com]
John G. Day, Esquire [jday@ashby-geddes.com]
Tiffany Geyer Lydon, Esquire [tlydon@ashby-geddes.com]
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
Wilmington, DE 19801

I further certify that on September 10, 2007, I caused a copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel and on the following non-registered participants in the manner indicated:

By E-Mail and Federal Express

Paul H. Berghoff, Esquire [berghoff@mbhb.com]
Joshua R. Rich, Esquire [rich@mbhb.com]
Jeremy E. Noe , Esquire [noe@mbhb.com]
MCDONNELL BOEHNEN HULBERT
& BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Karen L. Pascale

Josy W. Ingersoll (#1088)
Karen L. Pascale (#2903)
Karen E. Keller (#4489)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
Email: kpascale@ycst.com
Attorneys for Defendant, Barr Laboratories, Inc.